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COVINGTON & BURLING
1201 PENNSYLVANIA AVENUE, N.W.
washington, DC 20004-2401

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte
MELTON B. AFFRIME, CHRISTOPHER R. BANFIELD, SAMIR K. GUPTA, and DESMOND PADHI

Appeal 2007-3897[1]
Application 09/760,588
Technology Center 1600

DECIDED: February 20, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 69-84, all the claims remaining in the application. The claims stand rejected as anticipated by the prior art. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

STATEMENT OF THE CASE

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[1] Heard February 12, 2008.

"Desloratadine is . . . a non-sedating antihistamine" (Spec. 1: 9-10). The present invention is directed to "treating and/or preventing allergic and inflammatory conditions in a human by administering an amount of desloratadine for a time sufficient to produce a steady state mean plasma concentration of desloratadine to a human in need of such treating" (Spec. 1: 1-5).

Claims 69-84 stand rejected under 35 U.S.C. § 102(e) as anticipated by Kou (U.S. Patent 6,100,274, issued August 8, 2000).

Claims 69, 73, and 79 are representative, and read as follows:

69. A method of administering a pharmaceutical composition, wherein the method comprises:

administering the pharmaceutical composition, comprising desloratadine and a suitable, inert pharmaceutically acceptable carrier or diluent, to target a pharmacokinetic (pK) profile for desloratadine comprising an arithmetic or geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic or geometric mean time to maximum plasma concentration (T_{max}) of desloratadine of about 3 hours post dose.

73. A method of administering a pharmaceutical composition, comprising:

administering the pharmaceutical composition, comprising desloratadine and a suitable, inert pharmaceutically acceptable carrier or diluent, once a day for about 10 days, wherein said administering is carried out to target a pharmacokinetic (pK) profile comprising an arithmetic or geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic or geometric mean time to maximum plasma concentration (T_{max}) of desloratadine of about 3 hours post dose.

79. A method of achieving a pharmacokinetic (pK) profile of desloratadine that is safe and effective for treating nasal and non-nasal

symptoms of seasonal and perennial allergic rhinitis and for treating symptoms of chronic idiopathic urticaria in a human 12 years or older, comprising:

administering a dosage form comprising desloratadine and a suitable, inert pharmaceutically acceptable carrier or diluent, wherein said administering is carried out to target the pK profile and wherein the pK profile comprises an arithmetic or geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic or geometric mean time to maximum plasma concentration (T_{max}) of desloratadine of about 3 hours post dose.

FINDINGS OF FACT[2]

Kou

1. Kou teaches that descarbonylethoxyloratadine (i.e., desloratadine) is "suitable for oral administration to treat allergic reactions in mammals" (Kou, col. 1, ll. 14-19).

2. According to Kou, "[t]he anti-allergic effective amount of [desloratadine] for oral administration varies from about 1 to 50 mg/day, preferably about 2.5 to 20 mg/day and more preferably about 5 to 10 mg/day in single or divided doses. The most preferred amount is 5 mg, once a day" (Kou, col. 5, 43-48).

3. Kou does not specify the dosage regimen (i.e., the duration of treatment) for desloratadine, but indicates that it "may be varied depending upon the requirements of the patients . . . as well as the severity of the allergic condition being treated" (Kou, col. 5, ll. 49-52).

The Invention

[2] Abbreviated "FF".

4. According to the present Specification, "[f]ollowing oral administration of desloratadine dosed 5 mg once daily for 10 days to normal healthy subjects, the arithmetic mean time to steady state maximum plasma concentration (T_{max}) occurred at approximately 3 hours post dose on day 10 and an arithmetic mean steady state peak plasma concentrat[ion] (C_{max}) was approximately 4.0 ng/mL . . . ; the geometric mean time to steady state maximum plasma concentration (T_{max}) occurred at approximately 2.00 hours post dose on day 10 and the geometric mean steady state peak plasma concentration[ ] (C_{max}) was approximately 3.63 ng/mL" (Spec. 7: 23 to 8: 8, and Table 2).

5. Thus, in normal healthy subjects, administration of 5 mg of desloratadine per day, produced the pharmacokinetic profile recited in the claims beginning on or about the 10th day of administration.

6. According to the present Specification, administering 5 mg of desloratadine a day, in a single or divided dose, "for a time sufficient to produce a geometric mean steady state maximum plasma concentration of desloratadine in the range of about 2.90 ng/mL to about 4.54 ng/mL, or [an] arithmetic mean steady state maximum plasma concentration of desloratadine in the range of about 3.2 ng/mL to about 5.0 ng/mL" (Spec. 9: 12-16), "provide[s] a safe and effective method of treating and/or preventing allergic and inflammatory conditions of the skin or . . . airway passages . . . in a human more than 12 years old" (Spec. 9: 8-11).

DISCUSSION

"It is a general rule that merely discovering and claiming a new benefit of an *old* process cannot render the process again patentable." *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990). "[A] limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005) (citations omitted). As summarized in *Perricone, id.* at 1375-76:

> [A] prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." *Id.* (quoting *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). Moreover, "[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *Id.; see also Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

"Thus, when considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure." *Perricone,* 432 F.3d at 1378.

Contrary to Appellants' argument, then, the fact that Kou "does not discuss how to administer desloratadine in order to achieve an arithmetic or geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL . . . [and] an arithmetic or geometric mean

time to maximum plasma concentration (T_{max}) of desloratadine of about 3 hours post dose" (Br. 17), would be irrelevant *if* the reference described a protocol that would inherently accomplish that objective.

However, "[i]nherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991).

Essentially, the present claims require either 10 days of desloratadine administration to target the steady state pharmacokinetic profile recited in the claims (e.g., claim 73), or administration of desloratadine for a period of time sufficient to target or achieve the same profile (e.g., claims 69 and 79, respectively). Based on the evidence of record, this amounts to the same thing at a dose of 5 mg of desloratadine per day (FF 4, 5, 6).

Thus, the issue raised by this appeal is whether Kou discloses administering desloratadine, at 5 mg per day for a period of ten days, or in some other amount for a period of time that would target or produce the steady state pharmacokinetics specified by the claims.

As discussed above, Kou expressly teaches that 5 mg/day of desloratadine, in a single dose or divided doses, is an "anti-allergic effective amount" in mammals (FF 1, 2), but does not specify any particular period of treatment, except to say that the dosage regimen will vary with the requirements of the patient, as well as the severity of the allergic condition being treated (FF 3).

In the absence of a discussion of treatment duration in Kou, we find that the Examiner has not established an adequate factual basis for the

assertion that "one of ordinary skill in the art is able to readily envisage about 10 days of treatment from the disclosure of Kou" alone (Answer 5). Nor has the Examiner provided any other evidence that administering desloratadine according to Kou's teachings would necessarily target or achieve the steady state pharmacokinetic profile required by the present claims.

Accordingly, the rejection of claims 69-84 under 35 U.S.C. § 102(e), is reversed.

REVERSED

saj

COVINGTON & BURLING
1201 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20004-2401